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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,445	03/09/2001	Gary Van Nest	377882001300	7011
25226	7590	12/16/2004		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,445

Applicant(s)

NEST ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,9-12,14 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,9-12,14 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. In the prior action, mailed on June 14, 2004, claims 1-4, 6, 9-12, 14, and 23-26 were pending and rejected. The Applicant submitted arguments in traversal of the rejections in the Response of October 12, 2004.
2. Because this action raises new grounds of rejection, the action is being made Non-Final.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(Prior Rejection-Withdrawn)** Claims 1-4, 6, 9-12, 14, and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant traverses the rejection by arguing that the claims are directed to methods of delaying or reducing the severity of any symptom of papillomavirus infection. The rejection is therefore withdrawn.
5. **(Prior Rejection-Maintained)** Claims 1-4, 6, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These were rejected because it is unclear how the ISS can both delay the development of the lesion and be administered to the site of the lesion. It is noted that the claims are directed to the treatment of

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any symptom, and that the applicant has suggested other symptoms that may be treated.

However, the specification indicates that these symptoms "are associated with the lesions." Page

14. Thus, it is still unclear how the development of the symptoms can be delayed where the lesion is already present.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Restated and Maintained)** Claims 1-4, 6, 23, and 24 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of reducing the severity of a papillomavirus associated lesion when administered to the site of a lesion, does not reasonably provide enablement for methods of delaying the development of a symptom of a papillomavirus infection. This rejection is restated such that claims 1-4, 6, 9-12, 14, and 23-26 are rejected for exceeding the scope of enablement in that the Applicant has not enabled those in the art to delay, or reduce the severity of, an symptom of papilloma virus infection. It is noted that the Applicant identifies the slowing of the growth of a papilloma as a delaying of the development of a symptom of papillomavirus infection.

While the Applicant has demonstrated that the administration of an ISS to a papillomavirus-associated lesion results in a slowing of the development of the lesion, the Applicant has not demonstrated that the administration would result in the inhibition or reduction in the severity of any symptom associated with the infection. There is no indication as what

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effects the administration of an ISS would have on any of the other symptoms suggested by the Applicant in the specification. Additionally, for several of the symptoms (e.g., pain, hoarseness of voice, and breathing difficulties), it is not even clear how a reduction in such symptoms can be measured as the occurrence and severity of the symptoms vary from individual to individual.

Nor has the Applicant presented any evidence that demonstrates a correlation between the effects of the administration of the ISS to a lesion with a delay in the development of, or a reduction in the severity of, other symptoms of the infection. For example, the Applicant has nowhere shown that the stabilization of the growth of the lesions provides any indication as to the hoarseness of the voice, level of pain, any other symptom of the infection. Because it is not clear what the relationship is between the size or growth of a papilloma-associated lesion, and any other symptom of viral infection, it is not clear that method to reduce such growth would be equally effective in the treatment of any such other symptom.

8. **(Prior Rejection- Maintained)** Claims 1-4, 6, 9-12, 14, and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been described above. As was indicated above, the claims appear to be drawn to the treatment of any symptom of a papillomavirus infection through administration of an ISS in the absence of a viral antigen, to a papillomavirus-associated lesion. However, while the Applicant has demonstrated that the administration of an ISS may reduce the severity of a papillomavirus-associated lesion, the

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Applicant has not demonstrated that such treatment would have any effect on other symptoms of the viral infection.

The Applicant traverses this rejection on the basis that they have both identified the compounds used to delay or reduce the severity of the symptoms, and have identified other symptoms of the infection. However, the Applicant has demonstrated only that the administration of an ISS to the lesion results in a regression of the lesion. The Applicant has not measured the effect of the ISS on any of these other symptoms of the infection, or provided any comparison of the severity or occurrence of these symptoms in treated verses untreated animals. Because the Applicant has established only that the administration of the ISS reduces the severity of the severity and induces regression of the lesions, the Applicant has not demonstrated possession of a method of reducing the severity or delaying the onset of any symptom of papillomavirus infection. The rejection is therefore maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Withdrawn)** Claims 1-3, 6, 9-11, and 23-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Beutner et al. (J Am Acad Dermatol 38(2/1): 230-39) and Bauman et al. (Pediatr Clin N Am 43(6): 1385-401), and further in view of the teachings of Yamamoto et al., (Jpn J Cancer Res 85: 775-79- of record in the IDS of

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February 2002). The Applicant traverses this rejection in part because the references do not teach the use of the ISS sequences identified in the claims. This argument is found persuasive. The rejection is therefore withdrawn.

11. **(Prior Rejection- Restated and Maintained)** Claims 4 and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Beutner, Bauman, and Yamamoto, and further in view of either of Raz et al. (U.S. patent 6,514,948), and Schwartz et al. (WO 98/55495- of record in the Feb 2002 IDS). This rejection is extended to claims 1-3, 6, 9-11, 14, and 23-26 because the teachings of the Raz and Schwartz references makes up for any deficiencies in the teachings of Beutner, Bauman, and Yamamoto. This is because each of these two references indicates that an octamer comprising the additional -CG at the end of the AACGTT hexamer of Yamamoto retains the ISS' immunostimulatory activity, and would therefore have also been expected to be able to stimulate the production of interferon α (IFN- α). See e.g., Raz, columns 7-8; and Schwartz, pages 4, and 10.

The Applicant traverses this rejection on two grounds. First, the Applicant asserts that there is no motivation to combine the teachings of the references such that those in the art would administer an ISS to treat the symptoms of infection by papillomavirus. Second, the Applicant asserts that, even if there were such a suggestion, it would render the claimed methods as no more than obvious to try. These arguments are not found persuasive.

The Applicant first argues that the combination of these references do not teach or suggest the use of the ISS sequences indicated in the claims for the treatment of papillomavirus infections. The Applicant argues that it would not have been obvious to those in the art to

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substitute ISS sequences for the adjuvants of Beutner or Bauman for the treatment of such infections. The Applicant argues that this is because there was no recognition in the art that the different adjuvant compounds would have been functional equivalents for such treatment.

This argument is not found persuasive because, as was described in the prior action, the Bauman and Beutner references attribute the ability of adjuvants to treat such infections to their ability to stimulate interferon α (IFN- α) production. See e.g., Beutner, page 237 (suggest IFN- α as the source of the efficacy of adjuvant treatment); and Bauman, pages 1394-95 (teaching the efficacy of IFN- α itself in treating such infections). Each of the Yamamoto and the Schwartz references recognized that the disclosed ISS had the ability to stimulate IFN- α , and therefore it was recognized in the art that, with respect to the IFN- α inducing activity, ISS were recognized equivalents of other adjuvants used to treat papillomavirus infection.

The second argument in traversal of the rejection is that the references do not provide sufficient basis to find a reasonable expectation of success, and would therefore at best render the claimed methods obvious to try. This argument is also not found persuasive. This is because, as was described previously, it was recognized in the art that IFN- α was effective to treat papillomavirus infections. See, Bauman, *supra*. This, in addition to the teachings in the other references suggesting that other adjuvants' efficacy is due at least in part to their ability to induce IFN- α activity, provides sufficient basis for those in the art to have a reasonable expectation of success in the use of an ISS, which also induces the production of this cytokine, to treat papillomavirus infections. It is additionally noted that the Schwartz et al reference provides further grounds in an expectation of success by explicitly suggesting the use of the disclosed ISS

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for the treatment of papillomavirus infections. See e.g., claims 1, 56, and 62. As the Applicant has not provided any evidence to the contrary, the traversal is not found persuasive.

The rejection is therefore maintained for the reasons above, and the reasons of record.

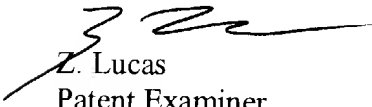
Conclusion

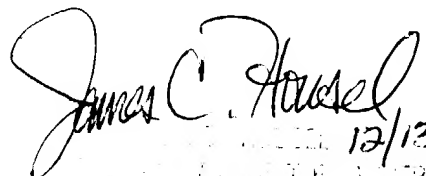
12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES C. HOUSEL
12/13/04
PATENT EXAMINER
ART UNIT 1648